

**REMARKS**

Claims 1-52 are pending in the application. Claims 1-39, 41-45, 48, and 50-52 are withdrawn from consideration. Claims 40 and 46 have been amended. Claim 49 has been canceled without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Upon entry of these amendments, Claims 40, 46, and 47 will be pending and under active consideration. Claims 40 and 46 are independent.

Applicants note that Claims 1-39, 41-45, 48, and 50-52 remain withdrawn from consideration without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications.

Applicants submit respectfully that the amendments presented herein are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

Claims 40 and 46 are amended herein to delete reference to the phrase "serine leukocyte protease inhibitor". Claims 40 and 46 have been also amended to now recite only at least one compound exhibiting  $\alpha_1$ -antitrypsin (AAT)-like activity. Finally, Claims 40 and 46 have been additionally amended to now recite that the compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl]-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. The amendment is supported fully by the claims and/or specification as originally filed and, thus, does not represent new subject matter. In particular, the amendment to Claims 40 and 46 finds support at page 34 , lines 3-7.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejections Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn**

The Office Action, at pages 2-4, rejects Claims 40, 46, 47, 49 under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner is of the opinion that the specification allegedly does not have support for the phrase "the first compound is not serine leukocyte protease inhibitor" as presently recited in Claims 40 and 46.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have canceled Claim 49, without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Accordingly, the rejection of Claim 49 under 35 U.S.C. § 112, first paragraph is moot and withdrawal thereof is respectfully requested.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have amended Claims 40 and 46 herein to delete reference to the phrase "serine leukocyte protease inhibitor".

In light of the amendment to Claims 40 and 46, Applicants respectfully submit that the rejection to Claims 40, 46, 47, 49 under 35 U.S.C. § 112, First Paragraph has been overcome. Accordingly, Applicants request respectfully that the rejection to Claims 40, 46, 47, 49 under 35 U.S.C. § 112, first paragraph be withdrawn.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

### **A. The Rejections Over Lezdey In View Of Rideout**

The Office Action, at pages 5-7, rejects Claims 40, 46, 47 and 49 as allegedly being obvious over Lezdey U.S. Patent No. 5,532,215) in view of U.S. Patent No. 4,818,538 to Rideout (hereinafter, "Rideout"), under 35 U.S.C. § 103(a) for the reasons of record. The Office Action alleges, in sum, that it would have been allegedly been obvious to one of ordinary skill to combine the two agents listed in Lezdey and Rideout in order to achieve additive effects. Applicants traverse respectfully.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have canceled Claim 49, without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Accordingly, the rejection of Claim 49 under 35 U.S.C. §103 is moot and withdrawal thereof is respectfully requested.

Without acquiescing in the arguments presented by the Office Action, Applicants have amended Claims 40 and 46 to now recite that the compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl)-2-(S)-methylpropyl]-L-prolinamide (CE-

2072) or a derivative thereof. Applicants respectfully submit that neither Lezdey alone nor the combination of Lezdey with Rideout teach or suggest the claimed method wherein the first compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl]-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Accordingly, neither Lezdey alone nor the combination of Lezdey with Rideout meets the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicants submit respectfully that the rejection of Claims 40, 46, 47, and 49, under 35 U.S.C. § 103(a) have been overcome, and Applicants request respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 103(a) be withdrawn.

**B. The Rejection Over Eisenberg In View Of Rideout**

The Office Action, at pages 7-9, rejects Claims 40, 46, 47, and 49 as allegedly being obvious over Eisenberg (U.S. Patent No. 6,017,880) in view of U.S. Rideout under 35 U.S.C. § 103(a) for the reasons of record. The Office Action alleges, in sum, that Eisenberg discloses that serine leukocyte protease inhibitor (SLPI) can inhibit HIV replication. The Office Action further alleges that it would have been obvious to one of ordinary skill to combine the two agents in order to achieve additive effects. Applicants traverse respectfully.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have canceled Claim 49, without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Accordingly, the

rejection of Claim 49 under 35 U.S.C. §103 is moot and withdrawal thereof is respectfully requested.

Without acquiescing in the arguments presented by the Office Action, Applicants have amended Claims 40 and 46 to now recite that the compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Applicants respectfully submit that neither Eisenberg alone nor the combination of Eisenberg with Rideout teach or suggest the claimed method wherein the first compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Accordingly, neither Eisenberg alone nor the combination of Eisenberg with Rideout meets the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicants submit respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 103(a) has been overcome, and Applicants request respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 103(a) be withdrawn.

**C. The Rejection Over Anderson or Vollenweider In View Of Rideout**

The Office Action, at pages 9-10, rejects Claims 40, 46, 47, and 49 as allegedly being obvious over either Anderson (J Biol Chem 268 24887, 1993) or Vollenweider F. (Biochemical Journal 314 ( Pt 2) 521-32, 1996) each taken in view of

U.S. Rideout under 35 U.S.C. § 103(a) for the reasons of record. The Office Action alleges that Anderson discloses that a mutant  $\alpha_1$ -antitrypsin is effective to inhibit HIV replication. The Office Action also alleges that Vollenweider discloses that the  $\alpha_1$ -antitrypsin mutant designated  $\alpha_1$ -PDX exhibits some degree of inhibition of HIV replication. The Office Action further alleges that it would have been obvious to one of ordinary skill to combine the two agents in each reference with retrovir as disclosed in Rideout in order to achieve additive effects. Applicants traverse respectfully.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have canceled Claim 49, without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Accordingly, the rejection of Claim 49 under 35 U.S.C. §103 is moot and withdrawal thereof is respectfully requested.

Without acquiescing in the arguments presented by the Office Action, Applicants have amended Claims 40 and 46 to now recite that the compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl)-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Applicants respectfully submit that neither Anderson or Vollenweider alone nor the combination of Anderson or Vollenweider with Rideout teach or suggest the claimed method wherein the first compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl)-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Accordingly, neither Anderson or Vollenweider alone nor

the combination of Anderson or Vollenweider with Rideout meets the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicants submit respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 103(a) has been overcome, and Applicants request respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 103(a) be withdrawn.

### **III. The Rejection Under 35 § 112, Second Paragraph Should Be Withdrawn**

The Office Action, at page 4, rejects Claims 40, 46, 47, and 49 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants traverse respectfully.

Without acquiescing in the propriety of arguments presented by the Office Action, Applicants have canceled Claim 49, without prejudice to pursuing the withdrawn subject matter in this or other continuation or divisional applications. Accordingly, the rejection of Claim 49 under 35 U.S.C. § 112, Second Paragraph is moot and withdrawal thereof is respectfully requested.

Without acquiescing in the arguments presented by the Office Action, Applicant has amended Claims 40 and 46 to now recite only at least one compound exhibiting  $\alpha_1$ -antitrypsin (AAT)-like activity. Additionally, Applicant has amended Claims 40 and 46

to now recite that the compound exhibiting AAT-like activity is a non-natural molecule comprising Benzyloxycarbonyl-L-valyl-N-[1-(2-(3-methylbenzyl)-1,3,4-oxadiazolyl)carbonyl]-2-(S)-methylpropyl]-L-prolinamide (CE-2072) or a derivative thereof. Moreover, Applicant respectfully draws the Examiner's attention to the Specification at page 34 , lines 3-7, wherein support is provided for the amendment to Claims 40 and 46, and more particularly, at page 34, lines 15-page 43, line 24, wherein numerous AAT-like derivatives are disclosed, as is the mouse model referred to in Example 3 as a way of testing whether or not a particular AAT-like derivative either does or does not show an equivalent antiviral activity compared to that of AAT. Thus, Applicant respectfully submits that the claims as amended are more than sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants submit respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 112, second paragraph, has been overcome, and Applicants request respectfully that the rejection of Claims 40, 46, 47, and 49 under 35 U.S.C. § 112, second paragraph, be withdrawn.



**CONCLUSION**

Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Serge Sira", with a stylized flourish underneath.

Serge Sira  
Registration No. 39,445  
Gilberto M. Villacorta, PH.D.  
Registration No. 34,038

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street, Suite 1600  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061  
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